BRIEFING PAPER
Microbial Commercial Activity Notice
J12-0003

PART I: BACKGROUND DATA

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Disposition Date: August 7, 2013

A. CBI Claims: Everything, including Submitter id; Microbial id; Use; Production volume; Process information; All attachments

B. Submitter: Solazyme, Inc., South San Francisco, CA

C. Genetically Engineered Microorganism (GEM): [redacted]

Donor: [redacted]

D. Production Volume (Colony Forming Units)(cfu):

Year 1: [redacted]
Year 2: [redacted]
Year 3: [redacted]

E. Use: [redacted]

F. Benefits: The genetic engineering adds new properties to the microorganism. The modified form of the alga [redacted]

PART II. RISK SUMMARY

Introduction

This intergeneric algal strain, [redacted]

[redacted]

Recipient Microorganism

[redacted]

[redacted]

Donor Microorganisms

[redacted]

Construct Analysis.

[redacted]

There is low hazard associated with the introduced genetic material. [redacted]

[redacted] There would be low concern for horizontal gene transfer of the inserted [redacted] gene to other organisms in the environment if it were to occur, [redacted]

Human Health Hazards

The concern for human health effects produced by the recipient microorganism, [redacted] is low. [redacted]

The concern for pathogenicity/toxicity from the introduced genetic material is also low. [redacted]

Ecological Hazards

[redacted]

Hazards to Animals

[redacted]

Hazards to Plants

[redacted]

Potential Survival of the Submission Microorganism in the Environment

The production strain [redacted] is expected to survive in the environment if inadvertently released from the [redacted] facility. It is capable of growth and survival in various environmental media, particularly in wet, muddy areas contaminated with organic matter. Survival and multiplication of [redacted] would be expected even through wastewater treatment.

PART III: ORGANISM CHARACTERISTICS RELEVANT TO INACTIVATION

[redacted]

PART IV: EXPOSURES AND RELEASES

Description of Operations:

[redacted]

[redacted]

A. Worker Exposure

Laboratory Activities: [redacted]
Inhalation exposure (bioaerosols): [redacted]
Dermal exposure: [redacted]
Personal Protective Equipment (PPE): gloves, glasses, and lab coats

Manufacturing and Processing Activities: [redacted]
Inhalation exposure (bioaerosols): [redacted]
Dermal exposure: [redacted]

B. Environmental Releases ([redacted]

Laboratory Activities
Laboratory propagation of stock culture ([redacted]

Potential releases to air are thought to be negligible as no aerosols are expected to be generated. Potential water releases are expected to be negligible [redacted]

Manufacturing
[redacted]

Releases to Air

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]

5. Drum dryer off-gas: negligible

Releases to Water

1. [redacted]

2. [redacted]

3. [redacted]

4. Off-gas treatment system wastewater [redacted]

Releases to Landfill

1. Disposal of spent biomass: [redacted]

C. Consumer, General Population, and Environmental Exposure

1. Consumer Exposure: The submission microorganism used to produce [redacted] is inactivated and separated from the [redacted] so consumer exposure is not expected.

2. General Population Exposure

There is a potential for the general population to be exposed to the alga as a result of releases to air and water from use of the submission microorganism at commercial scale.

Releases of solids to landfill from inactivated biomass were assumed to be disposed of in accordance with applicable state and/or federal regulations in a lined

landfill with leachate control. General population exposure from landfill disposal of inactivated biomass was, therefore, not assessed.

Inhalation Exposure – [redacted]

Inhalation exposure, surface water and drinking water exposure are expected to be negligible.

PART IV: RECOMMENDATION AND RATIONALE

There is low risk associated with Solazyme's proposed commercial scale production for the submission strain, [redacted]

Based on the amended information and data received from the submitter, it is recommended that MCAN J12-13 be dropped from further review.